IN THE UNITED STATES DISTRICT COURT

FOR THE WESTERN DISTRICT OF WASHINGTON

SHANNON TALKINGTON, individually, and as Personal Representative of the Estate of ELIZABETH BRADY, deceased,	**Civil Action No.:**
Plaintiffs,	**PLAINTIFF'S COMPLAINT FOR DAMAGES FOR WRONGFUL DEATH**
v.	**JURY TRIAL DEMANDED**
JOHNSON & JOHNSON and ETHICON, INC.,	
Defendants.	

COMPLAINT FOR DAMAGES FOR WRONGFUL DEATH

Come now Plaintiff, Shannon Talkington, individually, and as Personal Representative of the Estate of Elizabeth Brady, deceased ("Plaintiff"), by and through undersigned counsel, and brings this action against Defendants Ethicon, Inc. and Johnson & Johnson (hereinafter "Defendants"), and alleges as follows:

Parties

1. Plaintiffs are, and were, at all relevant times, citizens and residents of Washington and the United States.

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2. Plaintiff brings this action on behalf of the Estate and the Estate's beneficiaries for the survival claim and wrongful death of Elizabeth Brady, deceased, pursuant to RCW 4.20 *et seq.*

3. Defendant Johnson & Johnson ("J&J") is a corporation incorporated in New Jersey, and according to its website, the world's largest and most diverse medical device and diagnostics company, with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey. J&J has as its citizenship the State of New Jersey.

4. Defendant J&J organizes its subsidiary businesses into individual Business Units to coordinate the development, manufacture, testing, marketing promotion, training, distribution and sale of its products, including but not limited to its hernia repair mesh products. Within J&J there are three sectors: medical devices and diagnostics, pharmaceutical, and consumer. Within the medical devices and diagnostic sector are "Business Units" including the "Ethicon Franchise." The Ethicon Franchise was charged by J&J with the design, development, promotion, marketing, testing, training, distribution and sale of the hernia repair mesh products at issue in this case. The Company Group Chairman and Worldwide Franchise Chairman for the Ethicon Franchise, Gary Pruden, is employed by J&J. The companies which comprise the Ethicon Franchise are thus controlled by J&J and include, but are not limited to, Ethicon Inc.

5. Defendant Ethicon, Inc. ("Ethicon") is a wholly owned subsidiary of Defendant Johnson & Johnson. Defendant Ethicon is a corporation incorporated in the State of New Jersey with its principal place of business in Somerville, New Jersey. Ethicon is authorized and registered to transact business within the State of Washington. Ethicon has as its citizenship the State of New Jersey.

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6. Ethicon is a medical device company involved in the research, development, testing, manufacture, production, marketing, promotion and/or sale of medical devices including Physiomesh (hereinafter may be referred to as the "product").

7. J&J, directly and/or through the actions of Ethicon, has at all pertinent times been responsible for the research, development, testing, manufacture, production, marketing, promotion, distribution and/or sale of Physiomesh.

8. Defendants are individually, jointly and severally liable to Plaintiff for damages suffered by Plaintiff arising from the Defendants' design, manufacture, marketing, labeling, distribution, sale and placement of its defective mesh products at issue in the instant action, effectuated directly and indirectly through their respective agents, servants, employees and/or owners, all acting within the course and scope of their representative agencies, services, employments and/or ownership.

9. Defendants are vicariously liable for the acts and/or omissions of its employees and/or agents who were at all times relevant hereto acting on behalf of Defendants and within the scope of their employment or agency with Defendants.

Jurisdiction and Venue

10. This Court has subject-matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(a) based on complete diversity of citizenship between Plaintiff and all Defendants. The amount in controversy exceeds $75,000.

11. This Court has personal jurisdiction over each of the Defendants pursuant to the Washington Long-Arm Statute, § 4.28.185. Defendants transact business within the State of Washington, and Defendants committed tortious acts in Washington. Defendants' tortious acts caused injury to Plaintiff in the State of Washington. Defendants have purposefully engaged in the

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business of developing, manufacturing, publishing information, marketing, distributing, promoting and/or selling, either directly or indirectly, through third parties, as successor in interest, or other related entities, medical devices including Physiomesh in Washington, for which they derived significant and regular income. The Defendants reasonably expected that that their defective mesh products, including Physiomesh, would be sold and implanted in Washington.

12. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(2).

Facts Common To All Counts

13. On or about August 04, 2012, Plaintiff, Elizabeth Brady, had 10 x 15 cm Physiomesh Composite mesh, catalog number PHY1015V, implanted laparoscopically to repair a lower midline incarcerated ventral hernia.

14. Defendants manufactured, sold, and/or distributed the Physiomesh device to Plaintiff, Elizabeth Brady, through her doctors, to be used for treatment of hernia repair. On or about July 7, 2014, Plaintiff was forced to undergo a revision surgery due to complications from Defendant's defective hernia mesh. At revision, Plaintiff was found to have an incarceration of sigmoid colon and omentum in right lower quadrant hernia, exposed mesh and mesh adhesion to small intestine, perforation of the sigmoid colon proximal to the region of incarceration, and gross fecal spillage throughout the peritoneum. Plaintiff suffered physical pain, mental anguish, and death due to severe septic shock from sigmoid perforation, which resulted from defective hernia mesh. Defendants were responsible for the research, design, development, testing, manufacture, production, marketing, promotion, distribution and sale of Physiomesh, including providing the warnings and instructions concerning the product.

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15. Among the intended purposes for which Defendants designed, manufactured and sold Physiomesh was use by surgeons for hernia repair surgeries, the purpose for which the Physiomesh was implanted in Plaintiff.

16. Defendants represented to Plaintiff and Plaintiff's physicians that Physiomesh was a safe and effective product for hernia repair.

17. Defendants' Physiomesh was defectively designed and/or manufactured, was not reasonably safe for its intended use in hernia repair, and the risks of the design outweighed any potential benefits associated with the design. As a result of the defective design and/or manufacture of the Physiomesh, there was an unreasonable risk of severe adverse reactions to the mesh or mesh components including: chronic pain; recurrence of hernia; foreign body response; rejection; infection; inadequate or failure of incorporation/ingrowth; migration; scarification; deformation of mesh; improper wound healing; excessive and chronic inflammation; adhesions to internal organs; erosion; abscess; fistula formation; granulomatous response; seroma formation; nerve damage; tissue damage and/or death; and other complications.

18. Physiomesh has a unique design incorporating five (5) distinct layers: two layers of polyglecaprone-25 ("Monocryl") film covering two underlying layers of polydioxanone film ("PDS"), which in turn coat a polypropylene mesh. This design is not used in any other hernia repair product sold in the United States. The multi-layer coating was represented and promoted by the Defendants to prevent or minimize adhesion and inflammation and to facilitate incorporation of the mesh into the body, but it did not. Instead, the multi-layer coating prevented adequate incorporation of the mesh into the body and caused or contributed to an intense inflammatory and chronic foreign body response resulting in an adverse tissue reaction including migration and

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damage to surrounding tissue in the form of sclerotic, granulomatous and/or fibrotic tissue and improper healing.

19. When affixed to the body's tissue, the impermeable multi-layer coating of the Physiomesh prevents fluid escape, which leads to seroma formation, and which in turn can cause infection, abscess formation and other complications.

20. The multi-layer coating provides a breeding ground for bacteria in which the bacteria cannot be eliminated by the body's immune response, which allows infection to proliferate.

21. The multi-layer coating of Defendants' Physiomesh is cytotoxic, immunogenic, and not biocompatible, which causes or contributes to complications such as delayed wound healing, inflammation, foreign body response, rejection, infection, and other complications.

22. Defendants knew or should have known of the cytotoxic and immunogenic properties of the multi-layer coating of the Physiomesh prior to introducing it into the stream of commerce.

23. When the multi-layer coating of the Physiomesh is disrupted and/or degrades, the "naked" polypropylene mesh is exposed to the adjoining tissue and viscera, and can become adhered to organs, and cause damage to organs, and potentiate fistula formation.

24. These manufacturing and design defects associated with the Physiomesh were directly and proximately related to the injuries suffered by Plaintiff Elizabeth Brady.

25. Neither Plaintiff Elizabeth Brady nor her implanting physician were adequately warned or informed by Defendants of the defective and dangerous nature of Physiomesh. Moreover, neither Plaintiff Elizabeth Brady nor her implanting physician were adequately warned

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or informed by Defendants of the risks associated with the Physiomesh or the frequency, severity, or duration of such risks.

26. The Physiomesh implanted in Plaintiff Elizabeth Brady failed to reasonably perform as intended. The mesh caused serious injury and had to be surgically removed via invasive surgery, and necessitated additional invasive surgery to repair the hernia that the Physiomesh was initially implanted to treat.

27. Plaintiff Elizabeth Brady's severe adverse reaction, and the necessity for surgical removal of the Physiomesh, directly and proximately resulted from the defective and dangerous condition of the product and Defendants' defective and inadequate warnings about the risks associated with the product, and the frequency, severity and duration of such risks. Plaintiff Elizabeth Brady suffered both physical injury and pain and mental anguish, and death, and has incurred substantial medical bills and other expenses, resulting from the defective and dangerous condition of the product and from Defendants' defective and inadequate warnings about the risks associated with the product.

28. In May of 2016, Defendants issued an "Urgent: Field Safety Notice" relating to its Physiomesh Flexible Composite Mesh, the same product implanted in Plaintiff, and sent such notification to hospitals and medical providers in various countries worldwide. In this safety notice, Defendants advise these providers of "a voluntary product recall", citing two international device registries which reported data reflecting recurrence/reoperation rates after laproscopic placement as being higher than that observed from a data set relating to patient outcomes after being implanted with other mesh. However, in the United States, Defendants failed to issue a nationwide recall, opting instead to simply remove the product from shelves and cease further sales within the United States.

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COUNT I

Strict Product Liability: Defective Design

29. At the time the Physiomesh that was implanted in Plaintiff Elizabeth Brady's body, the product was defectively designed. As described above, there was an unreasonable risk that the product would not perform safely and effectively for the purposes for which it was intended, and Defendants failed to design against such dangers, and failed to provide adequate warnings and instructions concerning these risks.

30. Defendants expected and intended the Physiomesh product to reach users such as Plaintiff in the condition in which the product was sold.

31. The implantation of Physiomesh in Plaintiff's body was medically reasonable, and was a type of use that Defendants intended and foresaw when it designed, manufactured and sold the product.

32. The risks of the Physiomesh significantly outweigh any benefits that Defendants contend could be associated with the product. The multi-layer coating, which is not used in any other hernia mesh product sold in the United States, prevents tissue from incorporating into the mesh, leading to encapsulation, deformation, scarification and contraction, migration, erosion and rejection. The impermeable multi-layer coating leads to seroma formation, and provides a breeding ground for infection, and protects bacteria from being eliminated by the body's natural immune response.

33. The multi-layer coating of the Physiomesh, which was marketed, promoted and intended as a barrier against adhesion to the internal organs, was only temporary; it was expected and intended to degrade over time inside the body. Thus, this coating prevented tissue ingrowth in the short term, and degraded in the long-term, eventually leaving the "naked" polypropylene mesh

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exposed to the internal viscera and tissues. The degradation of this multi-layer coating caused or exacerbated an intense inflammatory and foreign body reaction. Once exposed to the viscera, the polypropylene mesh will inevitably adhere to the viscera, initiating a cascade of adverse consequences. Any purported beneficial purpose of the multi-layer coating (to prevent adhesion to the internal viscera and organs) was non-existent; the product provided no benefit while substantially increasing the risks to the patient.

34. The polypropylene mesh within the defective multi-layer coating of the Physiomesh was in itself dangerous and defective, particularly when used in the manner intended by Defendants in the Physiomesh. When implanted adjacent to the intestines and other internal organs, as Defendants intended for Physiomesh, polypropylene mesh is unreasonably susceptible to adhesion, bowel perforation or erosion, fistula formation and bowel strangulation or hernia incarceration, and other injuries.

35. The appropriate treatment for complications associated with Physiomesh involves additional invasive surgery to remove the mesh from the body, thus eliminating any purported benefit that the mesh was intended to provide to the patient.

36. Physiomesh was designed and intended for intraperitoneal implantation, which involved the product being implanted in contact with the intestines and/or other internal organs, which unnecessarily increased the risks of adhesion, erosion, fistula formation, and other injuries.

37. At the time the Physiomesh was implanted in Plaintiff, there were safer feasible alternative designs for hernia mesh products that would have prevented the injuries she suffered.

38. The Physiomesh product cost significantly more than competitive products because of its unique multi-layer coating, even though the multi-layer coating provided no benefit to consumers, and increased the risks to patients implanted with these devices.

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39. The Physiomesh implanted in Plaintiff failed to reasonably perform as intended, and had to be surgically removed necessitating further invasive surgery to repair the very issue that the product was intended to repair, and thus provided no benefit to her.

40. As a direct and proximate result of the defective and unreasonably dangerous condition of the product, Plaintiff suffered injuries and damages as summarized herein.

COUNT II

Strict Product Liability: Failure to Warn

41. At the time the Physiomesh that was implanted in Plaintiff's body, the warnings and instructions provided by Defendants for the Physiomesh were inadequate and defective. As described above, there was an unreasonable risk that the product would not perform safely and effectively for the purposes for which it was intended, and Defendants failed to design and/or manufacture against such dangers, and failed to provide adequate warnings and instructions concerning these risks.

42. Defendants expected and intended the Physiomesh product to reach users such as Plaintiff in the condition in which the product was sold.

43. Plaintiff and her physicians were unaware of the defects and dangers of Physiomesh, and were unaware of the frequency, severity and duration of the defects and risks associated with the Physiomesh.

44. The Defendants' Instructions for Use provided with the Physiomesh expressly understates and misstates the risks known to be associated specifically with the Physiomesh by stating that "Potential adverse reactions are those typically associated with surgically implantable materials." No other surgical mesh sold in the United States – and no other "surgically implantable material" – suffers the same serious design flaws as Physiomesh. No other device or material

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contains the dangerous and defective multi-layer coating, which itself causes or increases the risks of numerous complications, including prevention of incorporation, increased risk of seroma formation, immunologic response, increased risk for infection, and increased inflammatory reaction and foreign body response. Defendants provided no warning to physicians about the risks or increased risks specifically associated with the unique design of the Physiomesh.

45. The Defendants' Instructions for Use for the Physiomesh failed to adequately warn Plaintiff's physicians of numerous risks which Defendants knew or should have known were associated with the Physiomesh, including the risks of the product's inhibition of tissue incorporation, pain, immunologic response, dehiscence, encapsulation, rejection, migration, scarification, shrinkage/contraction, adhesion to internal organs and viscera, erosion through adjacent tissue and viscera, bowel obstruction, failure of repair/hernia recurrence, or hernia incarceration or strangulation.

46. Defendants failed to adequately train or warn Plaintiff or her physicians about the necessity for invasive surgical intervention in the event of complications, or how to properly treat such complications when they occurred.

47. Defendants failed to adequately warn Plaintiff or her physicians that the necessary surgical removal of the Physiomesh in the event of complications would leave the hernia unrepaired, and would necessitate further medical treatment to attempt to repair the same hernia that the failed Physiomesh was intended to treat.

48. Defendants represented to physicians, including Plaintiff's physician, that the multi-layer coating would prevent or reduce adhesion, and expressly intended for the Physiomesh to be implanted in contact with the intestines and internal organs and marketed and promoted the product for said purpose. Defendants failed to warn physicians that the multi-layer coating prevented tissue

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ingrowth, which is the desired biologic response to an implantable mesh device. Defendants failed to warn physicians that the multi-layer coating was only temporary and therefore at best would provide only a temporary adhesion barrier, and when the coating inevitably degraded, the exposed polypropylene would become adhered to the organs or tissue.

49. With respect to the complications that were listed in the Defendants' warnings, Defendants provided no information or warning regarding the frequency, severity and duration of those complications, even though the complications associated with Physiomesh were more frequent, more severe and lasted longer than those with safer feasible alternative hernia repair treatments.

50. If Plaintiff and/or her physicians had been properly warned of the defects and dangers of Physiomesh, and of the frequency, severity and duration of the risks associated with the Physiomesh, Plaintiff would not have consented to allow the Physiomesh to be implanted in her body, and Plaintiff physicians would not have implanted the Physiomesh in Plaintiff.

51. As a direct and proximate result of the inadequate and defective warnings and instructions, Plaintiff suffered injuries and damages as summarized herein.

COUNT III

Negligence

52. Defendants had a duty to use reasonable care in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, and preparing written instructions and warnings for Physiomesh, but failed to do so.

53. Defendants knew, or in the exercise of reasonable care should have known, that Physiomesh was defectively and unreasonably designed and/or manufactured, and was unreasonably dangerous and likely to injure patients in whom Physiomesh was implanted.

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Defendants knew or should have known that Plaintiff and Plaintiff's physicians were unaware of the dangers and defects inherent in the Physiomesh.

54. As a direct and proximate result of Defendants' negligence in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, and preparing written instructions and warnings for Physiomesh, Plaintiff suffered injuries and damages as summarized herein.

COUNT IV

Wrongful Death and Survival Claim

55. As a proximate cause of the defendant's negligence, gross negligence and/or recklessness, the plaintiff and statutory beneficiaries have sustained economic and non-economic damages, including those allowed by RCW 4.20 *et seq.*, and which include without limitation, past and future medical expense, past and future lost income or earning capacity, loss of consortium, emotional distress, grief, loss of enjoyment of life, inconvenience, mental anguish, the destruction of the spousal and child-parent relationships, and pain and suffering and in amounts to be proven at trial.

56. As a proximate cause of the defendant's wrongful acts and/or omissions, the Estate of Elizabeth Brady, deceased, has sustained damages including, without limitation, the loss of the accumulation of income and incurred medical, funeral, and burial expenses, and the conscious pain, suffering, anxiety and fear of impending death experienced by the decedent, in such amounts as will be proven at the time of trial together with interest thereon at the statutory rate from the date of death or the date the expenses were incurred.

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COUNT V

Punitive Damages

57. Defendants continued to manufacture and sell Physiomesh after obtaining knowledge and information that the product was defective and unreasonably unsafe. Defendants were aware of the probable consequences of implantation of the dangerous and defective Physiomesh, including the risk of failure and serious injury, such as suffered by Plaintiff Elizabeth Brady. Defendants willfully and deliberately failed to avoid those consequences, and in doing so, Defendants acted with conscious indifference, indifference to, and/or flagrant disregard of, the safety of those persons who might foreseeably have been harmed by the Physiomesh product, including Plaintiff, justifying the imposition of punitive damages.

PRAYER FOR RELIEF

WHEREFORE, as a result of the acts and omissions and conduct of Defendants set forth herein, Plaintiff Shannon Talkington, individually, and as Personal Representative of the Estate of Elizabeth Brady, deceased, is entitled to recover for Ms. Brady's personal injuries; past and present medical and related expenses; mental and physical pain and suffering; and Plaintiff is entitled to punitive damages in an amount sufficient to punish, penalize and deter Defendants from such conduct.

JURY DEMAND

Plaintiff demands trial by jury, judgment against Defendants, jointly and severally, for compensatory and punitive damages in an amount not less than $75,000, as well as costs, attorney fees, interest, or any other relief, monetary or equitable, to which she is entitled.

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DATED: June 5, 2017

Respectfully submitted,

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